Docket No. 22965.2111

In re Reissue Application for U.S. Patent No.: 5,498,240)
)
Inventors: Bagaoisan *et al.*)
)
Serial No.: To be assigned)
)
Filed: April 16, 1997) REISSUE APPLICATION TRANSMITTAL
)
For: INTRAVASCULAR CATHETER WITH A REPLACEABLE SHAFT SECTION)

The Assistant Commissioner of Patents
United States Patent and Trademark Office
Box Patent Application
Washington, D.C. 20231

SIR:

1. Transmitted herewith for filing is the above-identified reissue application

2. Enclosed are:
   ___x___ the papers required for a filing date under 37 C.F.R. §1.171
   ____12__ pages of specification including claims
   ____3__ sheets of drawings
   ___x___ Other Specify: Return Receipt Postcard

3. ___x___ Please Prepare a Title Report for U.S. Patent No. 5,498,240
4. ___x___ Please Transfer Drawings from the File of U.S. Patent No. 5,498,240
5. ___x___ Applicant hereby offers to surrender the original patent, U.S. Patent No. 5,498,240
6. _____ Applicant is a small entity entitled to a 50% reduction in fees
   _____ Verified statement enclosed

7. Filing Fee Calculations

	Number in Original Patent	Number Extra Over Original Patent	Rate	Basic Filing Fee $770.00
Total Claims	28 - 20 =	8	x $22.00 =	$176.00
Independent Claims	12 - 3 =	9	x $80.00 =	$720.00
____ Multiple dependent claims if any			x $260.00 =	$-0-

* If less than zero, enter "0".

Total Filing Fee $1,666.00

8. Additional Fees
   Title Report (37 C.F.R. §1.19(b)(4) $25.00
   Other Specify _____ ..... $-0-
   Total Fees Due $1,691.00

9. Fee Payment
   _____ **Payment of filing fee deferred**
   ___x___ Attached is a check in the amount of $ 1,691.00
   _____ Charge Deposit Account No.08-1641 in the amount of $ _____. A duplicate of this request is attached.
   ___x___ The Commissioner is hereby authorized to charge any additional fees which may be required or credit any overpayment to Deposit Account No. 08-1641 referencing Docket No. 22965.2111

By: _____
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Reissue Application of

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5,498,240

on

INTRAVASCULAR CATHETER WITH A REPLACEABLE SHAFT SECTION

Drawings: 3 Sheets
Docket No.: 22965.2111

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1,666,109 A

INTRAVASCULAR CATHETER WITH A REPLACEABLE SHAFT SECTION

BACKGROUND OF THE INVENTION

This invention generally relates to the field of intravascular catheters which are advanceable over a guidewire into a desired region of a patient's vasculature, and particularly to an intravascular catheter which is advanceable into a patient's coronary arteries for therapeutic or diagnostic procedures therein.

In percutaneous transluminal coronary angioplasty (PCTA) procedures, a guiding catheter having a preshaped distal tip is percutaneously introduced by a Seldinger techniques into the cardiovascular system of a patient and advanced within the system until the preshaped distal tip of the guiding catheter is disposed within the ascending aorta adjacent the ostium of the desired coronary artery. The guiding catheter is relatively stiff and when it is twisted or torqued from its proximal end, which extends outside the patient, the distal tip of the guiding catheter may be guided into the desired coronary ostium. With the distal end of the guiding catheter well seated within the ostium of the desired coronary artery, a balloon dilatation catheter is introduced into and advanced through the guiding catheter and out the distal tip thereof into the patient's coronary artery until the balloon on the distal extremity of the dilatation catheter is properly positioned across the lesion to be dilated. Once properly positioned, the balloon is inflated one or more times to a predetermined size with radiopague liquid at relatively high pressures (e.g., generally 4–12 atmospheres) to dilate the stenotic region of the diseased artery. When the dilatations have been completed, the balloon is finally deflated so that the dilatation catheter can be removed from the dilated stenosis to allow the resumption of increased blood flow through the dilated artery.

One frequently used type of angioplasty catheter is an over-the-wire type catheter which has an inner lumen extending within the catheter shaft which is configured to slidably receive a guidewire which facilitates advancement of the catheter over the guidewire to the desired location within the patient's coronary arteries. The guidewire receiving inner lumen may extend the entire length of the catheter as in conventional over-the-wire catheters or only in the distal portion of the catheter between a distal guidewire port and a proximal guidewire port which is spaced a short distance proximally from the distal guidewire port and a substantial distance from the proximal end of the catheter as in rapid exchange type catheters.

It is not uncommon during an angioplasty procedure to exchange the dilatation catheter once the dilatation catheter has been advanced within the patient's arterial system For example, if the physician determines that the inflated size of the balloon or the length of the balloon is inappropriate for the stenosis to be dilated, the dilatation catheter will be withdrawn and another, more appropriately sized dilatation catheter will be advanced into the coronary artery over the guidewire which remains in-place to dilate the stenosis. However, if the catheter is a conventional over-the-wire catheter, before the catheter is withdrawn either the guidewire in place must be replaced with an exchange wire, which is similar to the in-place guidewire except about twice as long, e.g. about 300 cm, as the normal guidewire or an extension wire about the same length as the in-place guidewire must be secured to the proximal end of the in-place guidewire to facilitate the withdrawal of the cath-

eter from the patient's vasculature without loss of the distal position of the guidewire. The reason that it is important to maintain the position of the distal tip of the guidewire across the stenosis, is that, if the guidewire is withdrawn, it may take the attending physician a substantial amount of time, e.g. from about 15 minutes up to about two hours or more, to advance a replacement guidewire into the patient's coronary artery and across the stenosis to be dilated and to then advance the dilatation catheter until the dilatation balloon thereof crosses the stenotic region. The original unsuitable catheter is usually discarded.

In some instances, after a dilatation is complete, it is necessary or at least desireable to implant a stent in the dilated stenotic region to provide long term patency thereto. In these cases the dilatation catheter which has performed the dilatation is removed and another balloon catheter having an unexpanded stent mounted about the balloon is advanced over the in-place guidewire to the stenotic region where the balloon is inflated to expand and thus implant the stent in the stenotic region. In this case the original angioplasty catheter is also discarded.

What has been needed and heretofore unavailable is a system for easily changing a shaft section of an intravascular catheter without the need to discard the entire catheter The present invention satisfies these and other needs

SUMMARY OF THE INVENTION

The present invention is directed to an intraluminal catheter with an exchangeable shaft section.

The intraluminal catheter of the invention has an elongated shaft having a proximal shaft section with at least one inner lumen extending therein and a distal shaft section with an inner lumen extending therein which is in communication with the inner lumen of the proximal shaft section Means are provided to releasably secure the proximal end of the distal shaft section to the distal end of the proximal shaft portion. The proximal end of the distal shaft section is provided with releasable connecting means which is configured to be connected to connecting means on the distal end of the proximal shaft section which allows the distal section to be readily exchanged for another distal section The preferred releasable connecting means are matching threads, male threads on the exterior of one shaft section member and female threads on the interior of another shaft section member which are configured to receive shaft section member with the male threads

In one aspect of the invention, the intraluminal catheter is a dilatation catheter for performing angioplasty procedures with a dilatation balloon on the distal shaft section thereof This allows the original distal shaft section to be exchanged for another distal shaft section when, for example, the dilatation balloon is of inappropriate size, either in length or in inflated diameter, for a particular stenotic region of the patient's artery.

The distal shaft section **42** of the above dilatation catheter may also be replaced when it is necessary or desireable to instal a stent in a dilated stenotic region of the patient's artery to ensure that the region remains patent after the dilatation In this case, the original distal shaft section is removed after the dilatation has been performed and a replacement distal shaft section having an inflatable balloon or other expandable means thereon with a stent mounted about the inflatable balloon or other expandable means The catheter with the replacement distal shaft section is advanced within the arterial system of the patient until the

inflatable balloon or other expandable means is disposed within the stenosis so expansion thereof expands the stent to secure the stent within the arterial passageway. The expanded balloon may then be deflated and the catheter removed from the patient with the expanded stent maintaining within the arterial passageway to maintain its patency.

In a presently preferred embodiment, the exchangeable catheter shaft section has an inner and an outer tubular member with the threaded connections on an end of either the outer tubular member or the inner tubular member or both which engage the matching treads on the mating ends of the tubular members of the shaft section which is not to be replaced when the threaded connections are made.

The above described advantages of the invention as well as others will become more apparent from the following detailed description of the invention when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an elevational view, partially in section, of an over-the-wire balloon dilatation catheter embodying features of the invention.

FIG. **2** is a transverse cross-sectional view of the catheter shown in FIG. **1** taken along the lines of **2—2**

FIG. **3**, is an elevational view, partially in section, of a rapid exchange type balloon dilatation catheter embodying features of the invention.

FIG. **4** is an elevational view of a distal portion of a balloon catheter embodying features of the invention with an expandable stent mounted on the balloon of the catheter with the balloon and the stent in expanded conditions within a stenotic region of a patient's artery

DETAILED DESCRIPTION OF THE INVENTION

With reference to FIGS **1** and **2**, dilatation catheter **10** embodying features of the invention includes an elongated catheter shaft **11** with a proximal section **12** and a replaceable distal section **13**. The proximal section **12** has an outer tubular member **14** and an inner tubular member **15** with the distal end of the outer tubular member having male threads **16** for connection to the distal section **13**. The distal section **13** has an outer tubular member **17** and an inner tubular member **18** with proximal end of the outer tubular member **17** having female threads **19** which are configured to engage the male threads **16** on the distal end of the outer tubular member **14** The distal end of the inner tubular member **15** of the proximal section **12** is tapered so as to scalingly fit into the inner passageway of the inner tubular member **18** of the distal section **13** when the outer tubular members **14** and **16** are threadably connected (as shown in phantom in FIG **1**). The outer tubular member **17** may be provided with webs or spacers (not shown) to centrally position the inner tubular member **18** within the outer tubular member **17** to ensure appropriate entry of the distal end of the inner tubular member **15** into the inner tubular member **18**

A dilatation balloon **22** is provided on the replaceable distal section **13** which has an interior in fluid communication with the annular inner lumen **23** defined between the inner and outer tubular members **18** and **17** and the annular lumen **24** defined between the outer and inner tubular members **14** and **15** of the proximal section **12**

A multiarm adaptor **25** is provided on the proximal end of the proximal section **12** to facilitate delivery of inflation fluid to the interior of dilatation balloon **22** through side arm **26** and annular lumens **23** and **24**. The inner tubular members **15** and **18** define a guidewire receiving lumen **27** which extends from the adapter **25** through the length of the catheter to a distal guidewire port **28** in the distal end of the distal placeable section **13** and is configured to slidably receive a guidewire **30**.

Due to strength requirements for the threaded connection between the outer tubular members **14** and **17**, it is usually preferable to form the threaded portions **31** and **32** of these members of a high strength material (e.g. stainless steel, NiTi alloys and the like). In this instance, the separate threaded connecting elements **31** and **32** would be formed independently of the other portions of the outer tubular members **14** and **17** and then secured to these members by a suitable adhesive or other means such as a fusion or solvent bond, depending upon the nature of the material from which the separate connecting elements **31** and **32** are formed. Other materials which are suitable for forming the connecting elements **31** and **32** include high strength polymers such as polycarbonate polymers and the like,

The dilatation catheter **10** depicted in FIGS. **1–2** may be used in a typical fashion whereby it is advanced over guidewire **30** previously disposed across the stenosis to be dilated until the balloon **22** extends across the lesion to be dilated. In the event the balloon's size, e.g. its inflated diameter or its length, is found to be inappropriate for the lesion to be dilated, the catheter **10** is withdrawn from the patient over the guidewire **30** and once outside of the patient, the removable distal section **13** and the proximal section **12** can be separated by twisting one or both so that the threaded members **31** and **32** can disengage. Another distal section of essentially the same construction, but with a balloon with a more appropriately sized length or inflated diameter, may then be threadably secured onto the distal end of the proximal section **12** and the reconstructed dilatation catheter may then be mounted onto the in-place guidewire and advanced over the guidewire until the more appropriately sized dilatation balloon crosses the stenosis An extension wire is usually secured to the proximal end of the guidewire **30** to facilitate the withdrawal of the original catheter **10** and the introduction and advancement of the replacement catheter with a new distal shaft section through the patient's arterial system until the more appropriately sized replacement balloon extends across the stenosis. The replacement balloon may then be inflated one or more times in a conventional manner to dilate the stenotic region of the patient's artery and then be withdrawn as the original catheter **10**.

FIG. **3** illustrates a rapid exchange type dilatation catheter **40** embodying features of the invention which has a proximal shaft section **41**, a distal shaft section **42**, a dilatation balloon **43** on the distal shaft section and an adaptor **44** on the proximal end of the proximal shaft section. The proximal shaft section **41** is preferably hypotubing formed of metal such as stainless steel (e.g. **304**) or pseudoelastic NiTi alloy provided with male threads **46** which are configured to threadably engage the female threads **47** on connector element **48** secured to the proximal end of distal shaft section **42**. As shown in FIG. **3**, the distal shaft section **42** is provided with a guidewire receiving inner lumen **50** which extends from proximal guidewire port **51** to the distal guidewire port **52** provided in the distal end of the catheter A dual lumen portion **53** extends from the connector element **48** to just within the proximal end of the balloon **43** and a tubular extension **54** thereof extends through the interior of

the balloon **43** and out the distal end thereof. A guidewire **55** is slidably disposed within the guidewire receiving inner lumen **50**. A radiopague marker **56** is provided on the tubular extension **54** at the midpoint between the two ends of the balloon **43** to facilitate the fluoroscopic observation thereof within the patient.

The distal shaft section **42** of the catheter **40** may be replaced as in the previously described embodiment, the only major difference being that there is no need for an extension wire to facilitate withdrawal of the original catheter **40** and the introduction of the replacement catheter with a different distal section.

FIG. **4** illustrates a replacement distal section **60** similar to the distal section **42** shown in FIG. **3** but adapted to deliver an expandable stent **61** to a stenotic region of a patient's artery to provide long term patency. Once the stent **61** is properly expanded, the balloon **63** may be deflated and the catheter withdrawn from the patient. This particular embodiment may be utilized after dilatation of the stenotic region by means of a catheter of the invention such as shown in FIG. **3**. In this instance, after the dilatation, the dilatation catheter may be withdrawn, the distal section **42** removed from the proximal shaft section **41** by disengaging the threaded ends of the proximal shaft section and connector element **48** and securing the replacement distal section **60** to the threaded end of proximal shaft section by threadably engaging the connector element **64** with female threads **65** to the distal end of the proximal shaft section with male threads **46** The replacement catheter with the distal section **60** may then be advanced into and through the patient's arterial system over the guidewire **66** until the balloon **63** is disposed across the stenosis. Expansion of the balloon **63** within the stenosis expands the stent **61** to hold open the stenotic region of the patient's artery. The catheter can then be removed with the stent remaining within the dilated arterial passageway to maintain its patency.

The catheter construction and the materials of the various portions thereof may be conventional Moreover, while the invention is described herein in terms of certain preferred embodiments, a variety of modification can be made. For example, threaded connections are described between the proximal and distal shaft sections to facilitate separation of the distal shaft section from the proximal shaft section However, other types of connections are contemplated with the present invention, the threaded connection being a presently preferred embodiment Other connections include projections and corresponding detentes. Additionally, while replacement of the distal shaft section is primarily described herein, those skilled in the art will recognize that the proximal shaft section may be the replaceable shaft section Other modifications and improvements may be made to the invention without departing from the scope thereof

What is claimed is

1 An intravascular catheter with an exchangeable shaft section, comprising.

a) an elongated tubular proximal shaft section having proximal and distal ends and a first inner lumen extending therein,

b) an elongated distal shaft section having proximal and distal ends, a port in the distal end of the distal shaft section, a second inner lumen extending therein in fluid communication with the first inner lumen in the proximal shaft section and a third inner lumen which is configured to slidably receive a guidewire and which extends therein to the port in the distal end of the distal shaft section, and

c) means to releasably interconnect the distal end of the proximal shaft section and the proximal end of the distal shaft section to effect fluid communication between the first and second inner lumens.

2. The intravascular catheter of claim **1** wherein an inflatable dilatation balloon is provided on the distal shaft section having an interior in fluid communicaion with the second inner lumen in the distal section.

3. The intravascular catheter of claim **1** wherein the connector means includes male threads on an end of one of the shaft sections and female threads on a mating end of the other shaft section which are configured to threadably engage the male threads

4. The intravascular catheter of claim **1** wherein the tubular proximal shaft section includes an inner tubular member disposed therein which has a fourth inner lumen which is configured to slidably receive a guidewire therein and which is in communication with the third inner lumen in the distal shaft section.

5. The intravascular catheter of claim **2** wherein means are provided on the proximal end of the proximal section for directing fluid through the first inner lumen extending therein and the second inner lumen in the distal section into the interior of the balloon.

6. A dilatation catheter with an exchangeable shaft section, comprising:

a) an elongated proximal shaft section having proximal and distal ends and an first inner lumen extending therein to the distal end;

b) an elongated distal shaft section having proximal and distal ends, a second inner lumen extending from the proximal end of the distal shaft section to a location spaced proximally from the distal end of the distal shaft section, a distal port in the distal end, a third inner lumen extending therein to and being in fluid communication with the distal port and being coextensive and parallel with at least part of the second inner lumen,

c) means to releasably connect the distal end of the proximal shaft section to the proximal end of the distal shaft section to effect fluid communication between the first inner lumen of the proximal shaft section and the second inner lumen of the distal shaft section; and

d) an inflatable dilatation balloon on the distal shaft section having an interior in fluid communication with the second inner lumen

7 The dilatation catheter of claim **6** wherein the connecting means include male threads on an end of one of the shaft sections and matching female threads on a mating end of the other shaft section

8. The dilatation catheter of claim **7** wherein the proximal shaft section includes inner and outer tubular members, the distal shaft section includes inner and outer tubular members and the threaded connecting means are on mating ends of the inner tubular members of the proximal and distal shaft sections.

9 The dilatation catheter of claim **7** wherein the proximal shaft section includes inner and outer tubular members, the distal shaft section includes inner and outer tubular members and the threaded connecting means are on mating ends of the outer tubular members of the proximal and distal shaft sections

10. A balloon catheter with an exchangeable shaft section, comprising:

a) an elongated proximal shaft section having proximal and distal ends and an first inner lumen extending therein to the distal end,

b) an elongated distal shaft section having proximal and distal ends, a second inner lumen extending from the proximal end of the distal shaft section to a location spaced proximally from the distal end of the distal shaft section, a distal port in the distal end of the distal shaft section, a third inner lumen extending within the distal shaft section to the distal port and a third inner lumen extending therein coextensive and parallel with at least part of the second inner lumen and being in fluid communication with the distal port;

c) means to releasably connect the distal end of the proximal shaft section and the proximal end of the distal shaft section to effect fluid communication between the first inner lumen of the proximal shaft section and the second inner lumen of the distal shaft section; and

d) an inflatable balloon on the distal shaft section having an interior in fluid communication with the second inner lumen.

11. The balloon catheter of claim **10** including an expandable stent which is mounted about the inflatable balloon in an uninflated condition and which is configured to expand upon the inflation of the balloon.

12. A method of treating a patient's body lumen, comprising:

a) providing an intraluminal catheter which has an elongated catheter shaft, a proximal shaft section, a replaceable distal shaft section and means to releasably connect the replaceable distal section with the proximal shaft section;

b) advancing the intraluminal catheter through a patient's body lumen until the catheter is disposed within a desired region thereof;

c) performing an intraluminal procedure within the body lumen with the intraluminal catheter;

d) withdrawing the intraluminal catheter from the patient;

e) removing the replaceable distal shaft section of the intraluminal catheter;

f) connecting a replacement distal shaft section to the proximal shaft section, and

g) advancing the intraluminal catheter with the replacement distal shaft section into the patient's body lumen until the intraluminal catheter is disposed within a desired region of the patient's body lumen.

13. A method of treating a patient's body lumen, comprising:

a) providing a dilatation catheter which has an elongated catheter shaft, a replaceable distal shaft section, a dilatation balloon on the replaceable distal shaft section, a proximal shaft portion and means to connect the proximal and distal shaft sections;

b) advancing the dilatation catheter through the patient's vasculature until the dilatation balloon is disposed within a stenotic region of a patient's artery,

c) withdrawing the dilatation catheter from the patient,

d) removing the replaceable distal shaft section of the catheter, and

e) connecting a replacement distal shaft section to the proximal shaft section, and

advancing the catheter with the replacement distal shaft section into the patient's vasculature until the catheter

is disposed within a desired region of the patient's vasculature

14. The method of claim **13** wherein the replacement distal shaft section has an inflatable balloon with an expandable stent mounted about the inflatable balloon and when the inflatable balloon and stent mounted thereon are disposed within the desired region of the patient's vasculature, inflating the balloon to expand the stent within the desired region of the vasculature and then deflating the balloon so that the catheter can be removed, leaving the expanded stent within the patient's vasculature.

15. A dilatation catheter comprising:

a) an elongated catheter shaft having proximal and distal ends, a guidewire port in the distal end, a guidewire receiving inner lumen extending to and being in fluid communication with the guidewire port and an inflation lumen extending to location proximal to the distal end;

b) a proximal shaft section having proximal and distal ends and at least part of the inflation lumen extenting therein to the distal end of the proximal shaft section; and

c) a replaceable distal shaft section having a proximal end, being releaseably connected by said proximal end of the distal shaft section to the distal end of the proximal shaft section, at least part of the inflation lumen extending within the distal shaft section distally therein from the proximal end of the distal shaft section to the location proximal to the distal end of the catheter shaft, and

d) a dilatation balloon on the distal shaft section surrounding the location having an interior in fluid communication with the portion of the inflation lumen extending within the distal shaft section

16 An intravascular catheter comprising:

a) a proximal shaft section having a proximal end, a distal end and an inner lumen extending therein;

b) a distal shaft section having a proximal end, a distal end, a port in the distal end, a second inner lumen extending therein in fluid communication with the inner lumen of the proximal shaft section and a third inner lumen extending parallel and at least partially coextensive with the second inner lumen within the distal shaft section and in fluid communication with the port in the distal end of the distal shaft section, and

c) means to releasably connect the proximal end to the distal shaft section to the distal end of the proximal shaft section

17. The intravascular catheter of claim **16** wherein the distal shaft section is releasably connected to the proximal shaft section by means of interconnecting threads on the distal end of the proximal shaft section and on the proximal end of the distal shaft section.

18. The intravascular catheter of claim **17** wherein the threads on the distal end of the proximal shaft section are male threads and the mating threads on the proximal end of the distal section are female threads.

19 The intravascular catheter of claim **17** wherein the proximal section is a metallic tube.

20. The intravascular catheter of claim **19** wherein the metallic proximal shaft section has male threads on the distal end thereof.

21 The intravascular catheter of claim **17** wherein the means to releasably connect the proximal end of the distal

shaft section to the distal end of the proximal shaft section includes an intermediate tubular element which has proximal and distal ends, threads on at least one of said ends which match the threads on the mating end of one of the shaft sections with the other of said ends of the intermediate tubular element being secured to the mating end of the other shaft section.

22. The intravascular catheter of claim 21 wherein threads are on the proximal end of the intermediate tubular element and the distal end of the proximal shaft section.

23. The intravascular catheter of claim 21 wherein threads are on the distal end of the intermediate tubular element and the proximal end of the distal shaft section.

* * * * *

24. A method for performing a medical procedure using a catheter comprising the steps of:

a) providing a catheter with a first catheter shaft section having a proximal end, a distal end and a first inner lumen extending therein to a location proximal to the distal end, a second catheter shaft section disposed proximal to the first catheter shaft section having a proximal end, a distal end and an inner lumen extending therein and a releasable connection between the distal end of the second catheter shaft section and the first catheter shaft section with the inner lumen within the first shaft section being in fluid communication with the inner lumen within the second catheter shaft section;

b) inserting the catheter into a patient over a guidewire disposed in part within the patient, with at least a portion of the second catheter shaft section extending out of the patient, to perform a medical procedure;

c) pulling the portion of the second shaft section extending out of the patient over the guidewire to withdraw at least part of the catheter shaft from the patient; and

d) disengaging one of the catheter shaft sections from the other catheter shaft section.

25. An intravascular catheter which comprises proximal and distal ends, a port in the distal end, a balloon connected to an inflation lumen, said balloon being carried adjacent said distal end, a guidewire lumen extending within the catheter to the port in the distal end, said catheter comprising a plurality of segments having connectors which are secured together in end-to-end relations to form said catheter, but which are both separable into separated segments by the user.

26. The method of removing an intravascular catheter from a patient's vascular system over a guidewire, which comprises: grasping said catheter and grasping said guidewire; partially withdrawing said catheter out of the vascular system of the patient while restraining the guidewire from retracting movement; removing a proximally mounted section of said catheter from the remainder of said catheter, and separately sliding said catheter section off of the guidewire while substantially continuously grasping the guidewire to prevent retracting movement thereof.

27. A method for withdrawing a catheter from a patient's vascular system, which comprises the steps of:

a) introducing a guidewire into said vascular system;

b) advancing a catheter in said vascular system over said guidewire, said catheter having at least a distal section and a proximal section releasably connected to the distal section;

c) withdrawing said catheter from said vascular system over said guidewire by first removing said proximal section while restraining said guidewire; and

d) thereafter removing said distal section while restraining said guidewire.

28. A catheter for introduction into and withdrawal from the vascular system of a patient over a guidewire in said vascular system, which comprises:

a) said catheter having a distal section and a proximal section;

b) said distal section and said proximal section being alternatively connectable and separable; and

c) said catheter being adapted for introduction into said vascular system over said guidewire and for withdrawal from said vascular system over said guidewire by removing said proximal section while restraining said guidewire and thereafter removing said distal section while restraining said guidewire.

#13921

[redacted]

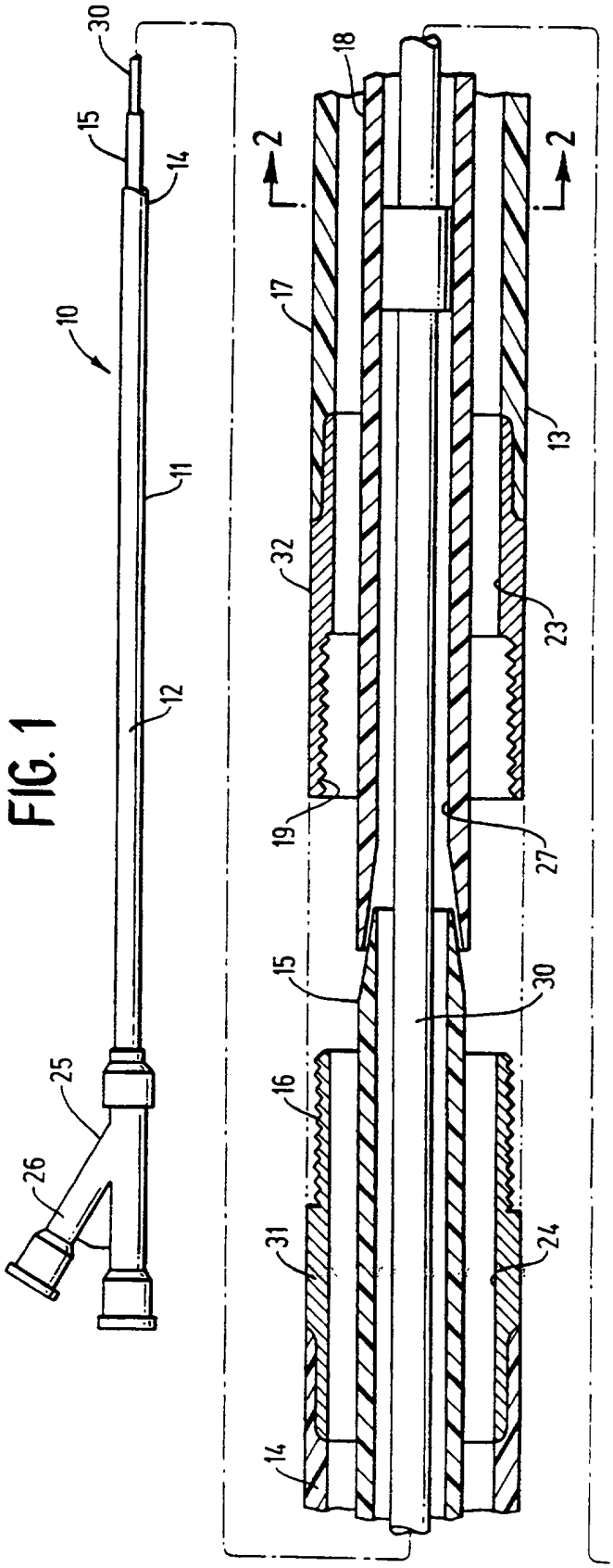


FIG. 1

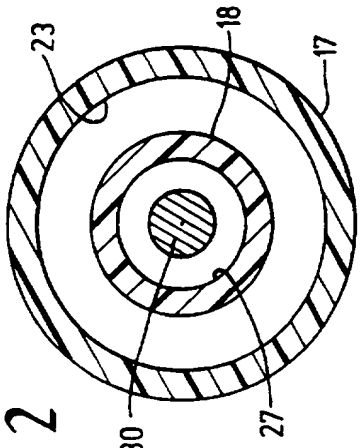
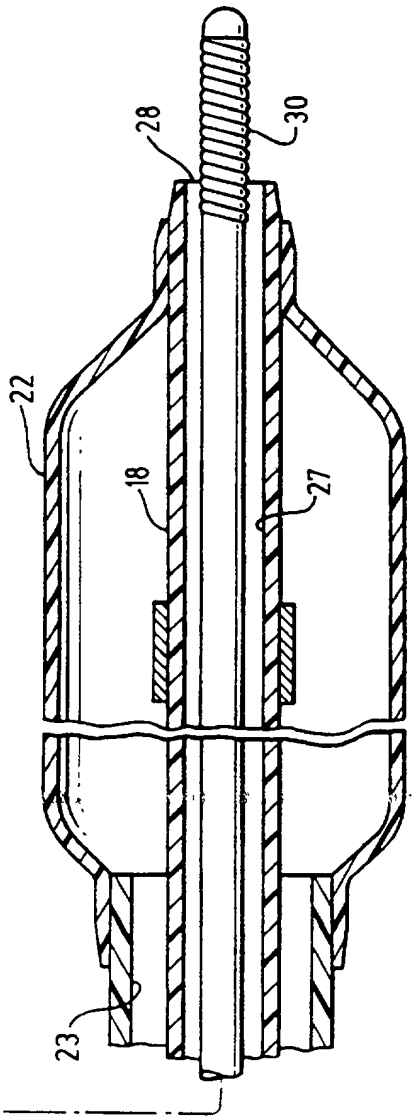


FIG. 2



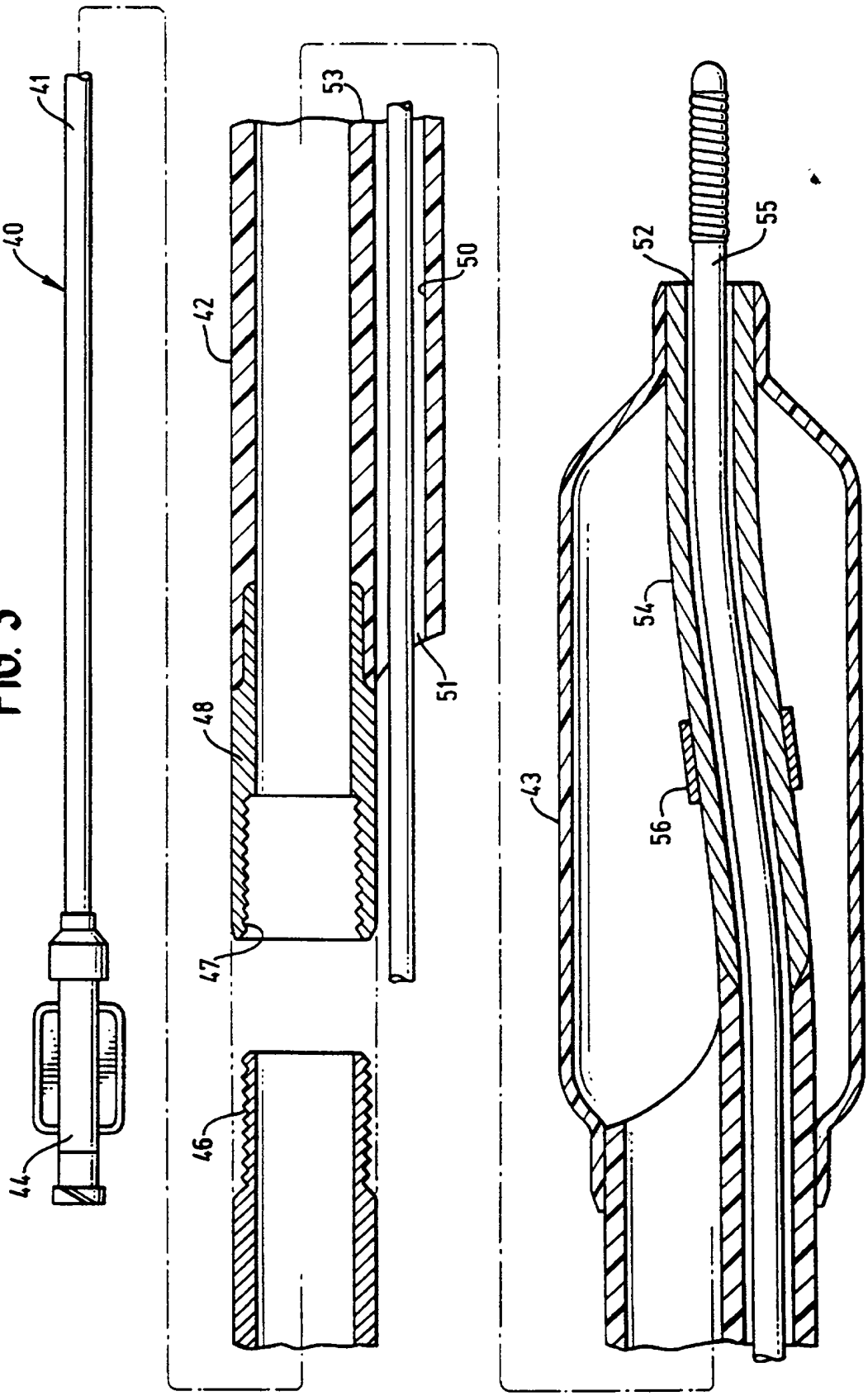


FIG. 3

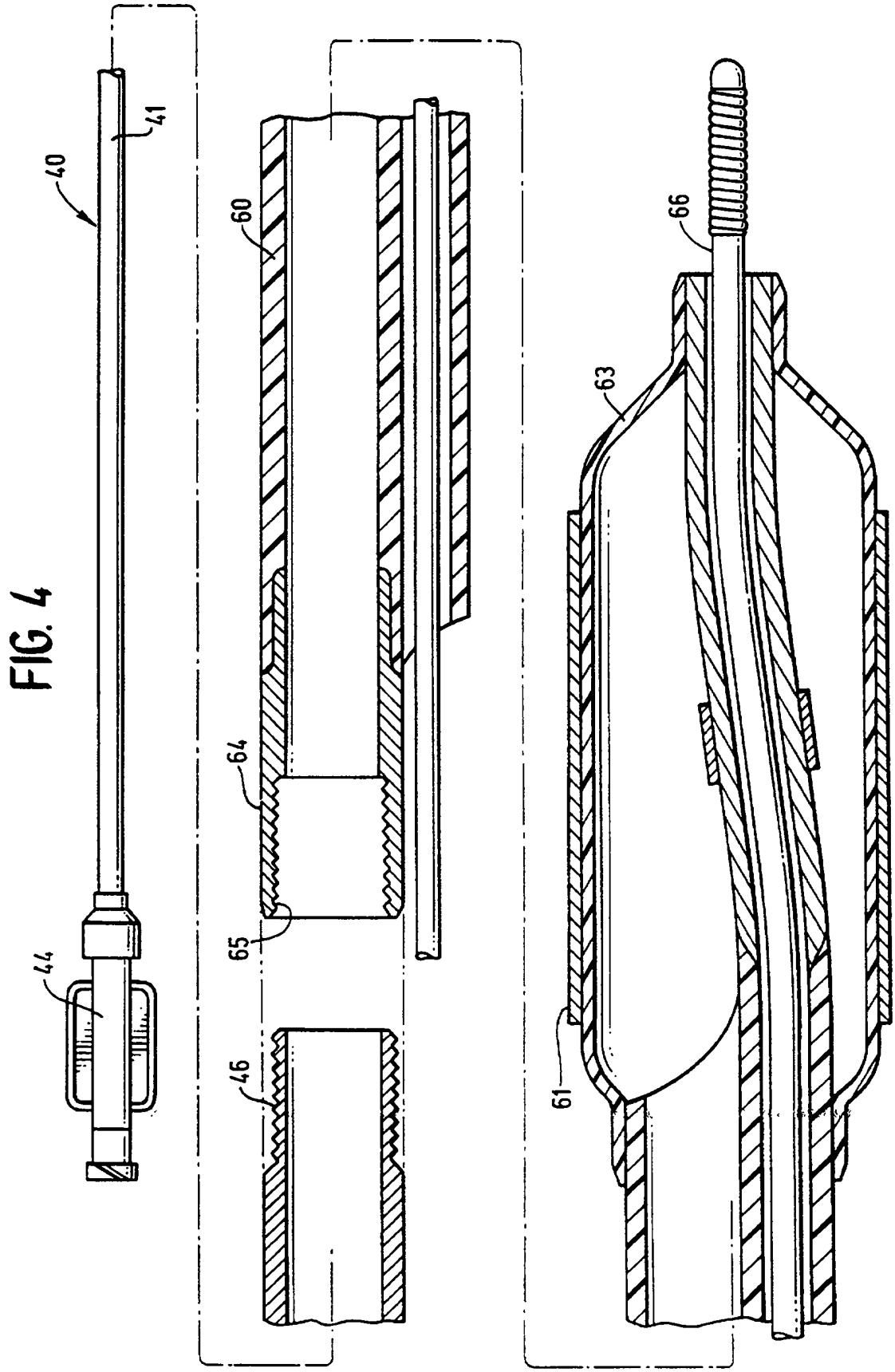


FIG. 4

EXHIBIT A

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FROM:	REFERENCE NUMBER	NUMBER OF PAGES	DATE
Nita J. Miller	22965-2111	1 (including cover page)	January 29, 1998

MESSAGE:

Further to my January 5, 1997, letter regarding the Reissue Application, entitled INTRAVASCULAR CATHETER WITH REPLACEABLE SHAFT SECTION, please be advised that today is the final deadline to file the Declaration and Power of Attorney with the Patent office.

Please contact me as soon as you receive this facsimile at (650) 324-7107, or simply send me the signature page of the Declaration via facsimile at the number referenced above.

Should you have any questions, please feel free to contact me. Thank you.

Yours truly,

Nita

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REISSUE #4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application for U.S.	)	Examiner:	Not yet assigned
Patent No.: 5,498,240	)	Group Art Unit:	3306
Issued: September 10, 1996	)	Docket No.:	22965-2111
Inventors: Bagaoisan *et al.*	)		
Serial No.: 08/843,711	)		
Filed: April 16, 1997	)		
For: **INTRAVASCULAR CATHETER WITH A REPLACEABLE SHAFT SECTION**	)	**RESPONSE TO NOTICE TO FILE MISSING PARTS OF APPLICATION**	

BOX MISSING PARTS
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In response to the Notice to File Missing Parts of Application - Filing Date Granted mailed July 29, 1997, transmitted herewith is Part 2 of the Notice to File Missing Parts of Application - Filing Date Granted; Declaration and Power of Attorney; Petition for Filing By Other Than All Inventors, under 37 C.F.R. § 1.47(a); Declaration of Nita Miller; Assent of Assignee to Reissue Application; and a return postcard.

Applicant is other than a small entity. Applicant hereby petitions for an Extension of Time of four (4) months, pursuant to 37 C.F.R. § 1.136(a).

Payment of Fees. Please charge the following fees to Deposit Account No. 08-1641, referencing Docket No. 22965-2111. The Commissioner is authorized to charge any additional fees and credit any overpayment which may be required in connection with this application to Deposit Account No. 08-1641, referencing Docket No. 22965-2111.

Extension Fee under 37 C.F.R. § 1.17(d)	$1,510.00
Surcharge fee under 37 C.F.R. § 1.27	130.00
Petition Fee under 37 C.F.R. §1.17(h)	130.00
TOTAL FEES:	$1,770.00

Respectfully submitted,

By: _____
William B. Anderson
Reg. No. P41,585

HELLER EHRMAN WHITE & McAULIFFE
525 University Avenue
Palo Alto, CA 94301-1900
Direct Dial: (650) 324-7127
Fax: (650) 324-0638

EJL:PM:njm

CERTIFICATE OF MAILING

I hereby certify that these papers are being deposited in the U.S. mail as first class with postage prepaid, addressed to: BOX MISSING PARTS, Assistant Commissioner for Patents, Washington D.C. 20231, on January 29, 1998, in Palo Alto, CA.

Nita J. Miller

REISSUE #4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application for	)	Examiner: Not yet assigned
	)	
Patent No.: 5,498,240	)	Group Art Unit: 3306
	)	
Issued: September 10, 1996	)	
	)	
Inventors: Bagaoisan, *et al.*	)	
	)	
Serial No.: 08/843,711	)	
	)	
For: **INTRAVASCULAR CATHETER WITH A REPLACEABLE SHAFT SECTION**	)	
	)	
Filed: April 16, 1997	)	
	)	
Docket No.: 22965.2111	)	

DECLARATION PURSUANT TO 37 C.F.R. § 1.175 AND POWER OF ATTORNEY

Assistant Commissioner for Patents
BOX REISSUE
United States Patent and Trademark Office
Washington, D.C. 20231

Dear Sir:

I depose and say that:

1. My residence, post office address and citizenship is as stated below next to my name.

2. I believe that I am an original, first and joint inventor of the subject matter which is claimed and for which a patent on the invention entitled **INTRAVASCULAR CATHETER WITH A REPLACEABLE SHAFT SECTION**, was granted on March 12, 1996 as U.S. Patent No. 5,498,240 ('240 patent), a copy of which is attached as Exhibit A.

3. I have reviewed and understand the contents of the specification of the '240 patent, including the claims.

4. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

5. I believe the '240 patent to be partly inoperative or invalid because of error without any deceptive intent on the part of the applicants, by reason of the fact that we claimed less than we had the right to claim in the original patent.

6. I believe that during prosecution of the application, the attorney handling the prosecution failed to claim aspects of the invention which we are entitled to claim. Claims 1, 6 and 12 of the '240 patent are unduly limited in several aspects, and claim 12 lacks certain desirable clarifying language which would effectively broaden the scope of the claim.

7. The invention is directed to a catheter having one or more exchangeable shaft sections, and a method of using the catheter. Claims 1, 6 and 12 have limitations which unnecessarily limit the scope of the invention claimed.

8. Claims 1 and 6 of the '240 patent are now unnecessarily limited to a catheter with an exchangeable shaft section and claim 12 is limited to a replaceable distal shaft section, whereas the invention disclosed in the patent includes exchangeable distal and proximal shaft sections.

9. Claim 6 has limitations which unnecessarily limit the scope of the invention claimed. Claim 6 now is limited to a dilatation catheter, whereas the catheter construction disclosed in the patent and contemplated by the invention is more broadly directed to an intravascular catheter.

10. Claim 12 has limitations which may unnecessarily limit the scope of the invention claimed. Claim 12 now is limited to treating a patient's body lumen, whereas the method disclosed in the patent is more broadly directed to a method of performing a medical procedure. Claim 12 requires removing the replaceable distal shaft section, and connecting a replacement distal shaft section to the proximal shaft section. The method disclosed in the patent broadly involved separating connected shaft sections and does not require connecting a replacement distal shaft section.

11. Claim 12 lacks clarifying language, namely, that the catheter is slid on and off a guidewire while the guidewire is restrained, and that the whole catheter is not withdrawn from the patient before the catheter shaft sections are separated.

12. On information and belief, the attorney handling the prosecution of the original application, Edward J. Lynch, through error without deceptive intent, failed to recognize the above described features of the invention in their broadest sense.

13. I am unaware how or when the error occurred but, on information and belief I believe that it occurred during the prosecution of the original application.

14. On information and belief, Edward J. Lynch, undertook a review of the '240 patent during the first quarter of 1997 and, as a result of his review, he concluded that he did not appreciate the breadth of the invention when he was prosecuting the original application.

15. On information and belief, as a result of Mr. Lynch's review, he recommended to the assignee, Advanced Cardiovascular Systems, Inc., that a reissue application be filed for the '240 patent within two years from the issue date thereof, so that the invention thereof could be claimed more broadly.

16. I have reviewed the new claims 24-28 which are included with the present reissue application as filed and new claims 29 and 30 which are presented by preliminary amendment, copies of which are attached hereto as Exhibit B, and believe that we were entitled to claim the invention set forth in these claims 24-30 at the time the original application for the above-referenced patent was made.

17. I hereby appoint the following attorneys and agents to prosecute this reissue application and to transact all business in the United States Patent and Trademark Office connected therewith:

EDWARD J. LYNCH, Registration No. 24,422
ALAN M. KRUBINER, Registration No. 26,289
WILLIAM SCHMONSEES, Registration No. 31,796
JACQUES DULIN, Registration No. 24,067
HERWIG von MORZE, Registration No. 29,484
WALTER KURZ, Registration No. 37,373
DEREK P. FREYBERG, Registration No. 29,250
PING CHOW, Registration No. 30,740
ROBERT DENNIS, Registration No. 40,988

of the firm

HELLER EHRMAN WHITE & McAULIFFE
525 University Avenue
Palo Alto, CA 94301-1900
(650) 324-7000

and

COLIN D. BARNITZ, Registration No. 35,061
WILLIAM A. BLAKE, Registration No. 30,548
GEORGE M. COOPER, Registration No. 20,201
FELIX J. D'AMBROSIO, Registration No. 25,721
DOUGLAS R. HANSCOM, Registration No. 26,600
JIM W. HELLWEGE, Registration No. 28,808
ERIC S. SPECTOR, Registration No. 22,495

of the firm:

JONES, TULLAR & COOPER, P.C.
2001 Jefferson Davis Highway
Box 2266, EADS Station
Arlington, VA 22202
Telephone: (703) 415-1500

Direct all correspondence to:

Edward J. Lynch
HELLER EHRMAN WHITE & McAULIFFE
525 University Avenue
Palo Alto, CA 94301-1900
Tel. No.: (650) 324-7000
Direct Dial: (650) 324-7098
Facsimile: (650) 324-0638

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful

false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of First Inventor: Celso S. J. Bagaoisan

Executed on ___ day of _____, 19__.

Inventor's Signature: _____
Residence: 4441 Pomponi Street, Union City, California 94587
Post Office Address: same as above
Citizenship: United States of America

Full name of Second Inventor: John P. Shanahan

Executed on ___ day of _____, 19__.

Inventor's Signature: _____
Residence: 61 Leigh Hill Road, Cobham Surrey, KT112HY, UK
Post Office Address: same as above
Citizenship: United States of America

Full name of Third Inventor: Ketan P. Muni

Executed on 6th day of January, 1998

Inventor's Signature Ketan P. Muni
Residence: 97 Frontier Trail Drive, San Jose, CA 95136
Post Office Address: same as above
Citizenship: India U.S.A.

Full name of Fourth Inventor: Elizabeth N. Hammack

Executed on ___ day of _____, 19__.

Inventor's Signature _____
Residence: 12781 W. Sunset Hills Drive, Los Altos Hills, CA 94022
Post Office Address: same as above
Citizenship: United States of America

Full name of Fifth Inventor: Robert M. Abrams

Executed on ___ day of _____, 19__.

Inventor's Signature: _____
Residence: 359 Redondo Terrace, Sunnyvale, CA 94086
Post Office Address: same as above
Citizenship: United States of America

Full name of Sixth Inventor: James C. Peacock, III

Executed on ___ day of _____, 19__.

Inventor's Signature: _____
Residence: 526 East Evelyn Avenue, Sunnyvale, CA 94086
Post Office Address: same as above
Citizenship: United States of America

Full name of Seventh Inventor: William S. Tremulis

Executed on 29 day of January, 1998

Inventor's Signature _____
Residence: 97 Pelican Lane, Redwood City, CA 94065
Post Office Address: same as above
Citizenship: United States of America

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Full name of Fourth Inventor: Elizabeth N. Hammack

Executed on ___ day of _____, 19__.

Inventor's Signature _____
Residence: 12781 W. Sunset Hills Drive, Los Altos Hills, CA 94022
Post Office Address: same as above
Citizenship: United States of America

Full name of Fifth Inventor: Robert M. Abrams

Executed on 6 day of JANUARY, 1998.

Inventor's Signature: _____
Residence: 359 Redondo Terrace, Sunnyvale, CA 94086
Post Office Address: same as above
Citizenship: United States of America

Full name of Sixth Inventor: James C. Peacock, III

Executed on ___ day of _____, 19__.

Inventor's Signature: _____
Residence: 526 East Evelyn Avenue, Sunnyvale, CA 94086
Post Office Address: same as above
Citizenship: United States of America

Full name of Seventh Inventor: William S. Tremulis

Executed on ___ day of _____, 19__.

Inventor's Signature _____
Residence: 97 Pelican Lane, Redwood City, CA 94065
Post Office Address: same as above
Citizenship: United States of America

Full name of Fourth Inventor: Elizabeth N. Hammack

Executed on 6 day of January, 1998.

Inventor's Signature Elizabeth N. Hammack
Residence: 12781 W. Sunset Hills Drive, Los Altos Hills, CA 94022
Post Office Address: same as above
Citizenship: United States of America

Full name of Fifth Inventor: Robert M. Abrams

Executed on ___ day of _____, 19__.

Inventor's Signature: _____
Residence: 359 Redondo Terrace, Sunnyvale, CA 94086
Post Office Address: same as above
Citizenship: United States of America

Full name of Sixth Inventor: James C. Peacock, III

Executed on ___ day of _____, 19__.

Inventor's Signature: _____
Residence: 526 East Evelyn Avenue, Sunnyvale, CA 94086
Post Office Address: same as above
Citizenship: United States of America

Full name of Seventh Inventor: William S. Tremulis

Executed on ___ day of _____, 19__.

Inventor's Signature _____
Residence: 97 Pelican Lane, Redwood City, CA 94065
Post Office Address: same as above
Citizenship: United States of America

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application for U.S.	Examiner: Not yet assigned
Patent No.: 5,498,240 Issued: September 10, 1996	Group Art Unit: 3306
Inventors: Bagaoisan et al.	Docket No.: 22965-2111
Serial No.: 08/843,711 Filed: April 16, 1997	
For: **INTRAVASCULAR CATHETER WITH A REPLACEABLE SHAFT SECTION**	

PETITION FOR FILING BY OTHER THAN ALL INVENTORS PURSUANT TO 37 C.F.R. § 1.47(a)

BOX MISSING PARTS
Assistant Commissioner for Patents
United States Patent and Trademark Office
Washington, D.C. 20231

Dear Sir:

Applicant hereby petitions for acceptance of the declarations of signing joint inventors Ketan P. Muni, Elizabeth N. Hammack, Robert M. Abrams, and William S. Tremulis on behalf of all joint inventors: Celso S. J. Bagaoisan, John P. Shanahan, Ketan P. Muni, Elizabeth N. Hammack, Robert M. Abrams, James C. Peacock III, and William S. Tremulis, with the aforementioned signing joint inventors declaring on behalf of the non-signing inventors pursuant to MPEP 409.03(a). This petition is made for the reason that after diligent effort to obtain the declarations of Celso S. J. Bagaoisan, John P. Shanahan, and James C. Peacock III, counsel for applicants was unable to obtain said declarations. On various dates from January 5, 1998 to January 7, 1998, assistant to applicant's counsel, Nita J. Miller, forwarded by Federal Express a request for declaration to all joint inventors at their respective last know addresses. As of the time of the filing of this petition, no response has been received from the non-signing joint inventors, Celso S. J. Bagaoisan, John P. Shanahan, and James C. Peacock III. Filed with and in support of this petition is the declaration of Nita J. Miller regarding the facts

surrounding the unavailability of the aforementioned inventors, and a list of the last known addresses of the unavailable inventors below.

Last known addresses and telephone numbers of non-signing joint inventors:

Celso S. J. Bagaoisan
4441 Pomponi Street
Union City, California 94587
(510) 471-0747

John P. Shanahan
1530 Barn Owl Place
Santa Rosa, CA 95409
(707) 579-2620

James C. Peacock, III
526 East Evelyn Avenue
Sunnyvale, CA 94086
(408) 245-9427

Respectfully submitted,

By: _____
William B. Anderson
Attorney for Applicants
Registration No. P41,585

HELLER EHRMAN WHITE & McAULIFFE
525 University Avenue
Palo Alto, CA 94301-1900
Direct Dial: (650) 324-7127
Telephone: (650) 324-7000
Facsimile: (650) 324-0638

WBA:njm

HEWM #65074

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application for U.S.	)	Examiner: Not yet assigned
	)	
Patent No.: 5,498,240	)	Group Art Unit: 3306
Issued: September 10, 1996	)	
	)	Docket No.: 22965-2111
Inventors: Bagaoisan *et al.*	)	
	)	
Serial No.: 08/843,711	)	
Filed: April 16, 1997	)	
	)	
For: **INTRAVASCULAR CATHETER WITH A REPLACEABLE SHAFT SECTION**	)	

DECLARATION OF NITA J. MILLER IN SUPPORT OF PETITION FOR FILING BY OTHER THAN ALL INVENTORS PURSUANT TO 37 C.F.R. § 1.47(e)

BOX MISSING PARTS
Assistant Commissioner for Patents
United States Patent and Trademark Office
Washington, D.C. 20231

Dear Sir:

I, Nita J. Miller, depose and say that:

1. I have been a Patent Assistant to Edward J. Lynch, Applicants' Attorney, with HELLER EHRMAN WHITE & McAULIFFE since July 1997. However, I have been employed as a Patent Assistant since October 1991.

2. On January 5, 1998, I forwarded a letter to James C. Peacock, III, via Federal Express, to 526 East Evelyn Avenue, Sunnyvale, CA 94086. I enclosed therewith a Declaration and Power of Attorney for his signature in connection with the above-referenced matter, and a return self-addressed, postage prepaid Federal Express envelope. A copy of said letter is attached hereto as Exhibit A. On January 29, 1998, I telephoned James Peacock, III at his residence (408) 245-9427, however, his listed telephone number was being forwarded to a facsimile machine. On January 29, 1998, I sent a facsimile message to James C. Peacock, III, at (408) 245-9427, requesting that he send to me via facsimile the signature page of the Declaration and Power of Attorney or that he contact me immediately. A copy of said facsimile message

together with a copy of the confirmation of transmission are attached hereto as Exhibit A. To date, I have not received a response of any kind.

3. On January 5, 1998, I forwarded a letter to Celso S.J. Bagaoisan, via Federal Express, to 4441 Pomponi Street, Union City, CA 94587. I enclosed therewith a Declaration and Power of Attorney for his signature in connection with the above-referenced application, and a return self-addressed, postage prepaid Federal Express envelope. A copy of said letter is attached hereto as Exhibit B. On January 29, 1998, I left a voice message for Celso S.J. Bagaoisan at his residence telephone (510) 471-0747. To date, I have not received a response of any kind.

4. On January 7, 1998, I forwarded a letter to John P. Shanahan, via Federal Express, to 1530 Barn Owl Place, Santa Rosa, CA 95409. I enclosed therewith a Declaration and Power of Attorney for his signature in connection with the above-referenced application, and a return self-addressed, postage prepaid Federal Express envelope. A copy of said letter is attached hereto as Exhibit C. On January 29, 1998, I telephoned John P. Shanahan at his residence (707) 579-2620, and there was no answer. To date, I have not received a response of any kind.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such wilful false statements may jeopardize the validity of this application or any reissue patent issued thereon.

Executed this 29th day of January, 1998, at Palo Alto, California

By: Nita J. Miller
Nita J. Miller

surrounding the unavailability of the aforementioned inventors, and a list of the last known addresses of the unavailable inventors below.

Last known addresses and telephone numbers of non-signing joint inventors:

Celso S. J. Bagaoisan
4441 Pomponi Street
Union City, California 94587
'510) 471-0747

ı P. Shanahan
1 Barn Owl Place
Sar. ɔsa, CA 95409
(707) '-2620

James C. Peacock, III
526 East Evelyn Avenue
Sunnyvale, CA 94086
(408) 245-9427

Respectfully submitted,

By: WB Anderson

William B. Anderson
Attorney for Applicants
Registration No. P41,585

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WBA:njm

HEWM #65074